IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CEPHALON FRANCE,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 1:10-CV-00210-GMS
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

ANSWER AND COUNTERCLAIM

Defendants, Lupin Pharmaceuticals, Inc. ("Lupin Pharma") and Lupin Limited ("Lupin Ltd.") (collectively "Lupin"), by and through their attorneys, respond to the averments made in the numbered paragraphs of the complaint filed by Plaintiffs, Cephalon, Inc. and Cephalon France (collectively "Cephalon"), as follows:

Parties

Complaint Paragraph 1: Cephalon, Inc. is a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon, Inc. is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

Answer: On information and belief, Lupin admits the allegations in paragraph 1.

Complaint Paragraph 2: Cephalon France, is a société par actions simplifiée ("SAS") under the laws of France, a wholly-owned subsidiary of Cephalon, Inc., and located at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

Answer: On information and belief, Lupin admits the allegations in paragraph 2.

Complaint Paragraph 3: On information and belief, Lupin Limited ("Lupin Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India.

Answer: Lupin admits the allegations in paragraph 3 except the reference to "Bandra (W)."

Complaint Paragraph 4: On information and belief, Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation organized and existing under the laws of Virginia and having a principal place of business at Harborplace Tower, III South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

Answer: Lupin admits the allegations in paragraph 4.

Complaint Paragraph 5: On information and belief, Lupin Pharma, is a wholly-owned subsidiary and agent of Lupin Ltd.

Answer: With respect to paragraph 5, Lupin admits only that Lupin Pharma is a wholly-owned subsidiary of Lupin Ltd. Lupin denies the remaining allegations in paragraph 5.

Complaint Paragraph 6: On information and belief, Lupin Pharma, itself and on behalf of its parent corporation Lupin Ltd., distributes, markets, and/or sells generic drugs in Delaware and throughout the United States.

Answer: With respect to paragraph 6, Lupin admits only that Lupin Pharma markets or sells pharmaceutical products in the United States. Lupin denies the remaining allegations in paragraph 6.

Complaint Paragraph 7: On information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary and agent Lupin Pharma, is in the business of making and selling

generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

Answer: With respect to paragraph 7, Lupin admits only that Lupin Ltd. manufactures pharmaceutical products. Lupin denies the remaining allegations in paragraph 7.

Jurisdiction and Venue

Complaint Paragraph 8: Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Answer: With respect to paragraph 8, Lupin admits only that Cephalon purports to base subject-matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a) and purports to base venue on 28 U.S.C. §§ 1391 and 1400(b). Lupin will not contest venue in this judicial district solely for purposes of this action. But Lupin denies engaging in any act that violates the patent laws of the United States, and specifically denies any act resulting in liability for patent infringement. In addition, Lupin denies that subject-matter jurisdiction exists based on any act by Lupin Pharma, and therefore denies that Lupin Pharma is a proper party. Lupin denies any remaining allegations in paragraph 8.

Complaint Paragraph 9: This Court has personal jurisdiction over Lupin Ltd. and Lupin Pharma by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

Answer: Lupin denies the allegations in paragraph 9, but Lupin does not contest personal jurisdiction in this judicial district solely for purposes of this action.

Nature of This Action

Complaint Paragraph 10: This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 200751 filed by Lupin with the United States Food and Drug Administration ("FDA") for approval to market generic copies of Cephalon's successful Nuvigil® pharmaceutical products that are sold in the United States.

Answer: With respect to paragraph 10, Lupin admits only that this is a patent-infringement action arising under the patent laws of the United States that relates to ANDA No. 200751 filed by Lupin Ltd. with the FDA. Lupin denies the remaining allegations in paragraph 10.

Complaint Paragraph 11: Cephalon, Inc. is the holder of approved New Drug Application ("NDA") No. 21-875 for the use of Nuvigil® (armodafinil) tablets in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths, as indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, and shift work sleep disorder.

Answer: With respect to paragraph 11, Lupin admits only that Cephalon, Inc. is identified as the holder of NDA No. 21-875 for Nuvigil® (armodafinil) tablets in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths for certain FDA-approved indications. Lupin denies the remaining allegations in paragraph 11.

Complaint Paragraph 12: Cephalon, Inc. is the owner by assignment, and has the right to sue for infringement, of U.S. Reissue Patent No. RE37, 516 E ("the '516 patent"), entitled "Acetamide Derivative Having Defined Particle Size." The '516 patent was duly and legally

issued by the United States Patent and Trademark Office on January 15, 2002. A true and correct copy of the '516 patent is attached as Exhibit A.

Answer: With respect to paragraph 12, Lupin admits only that what appears to be a copy of the '516 patent is attached as Exhibit A to the complaint, that it identifies Cephalon, Inc. as the assignee, that it is entitled "Acetamide Derivative Having Defined Particle Size," and that the '516 patent issued on January 15, 2002. Lupin specifically denies that the PTO duly and legally issued the '516 patent. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding patent ownership and entitlement to sue for infringement, and therefore denies these allegations. Lupin denies any remaining allegations in paragraph 12.

Complaint Paragraph 13: Cephalon France is the owner by assignment, and has the right to sue for infringement, of U.S. Patent No. 7,132,570 ("the '570 patent"), entitled "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil." The '570 patent was duly and legally issued by the United States Patent and Trademark Office on November 7, 2006. A true and correct copy of the '570 patent is attached as Exhibit B.

Answer: With respect to paragraph 13, Lupin admits only that what appears to be a copy of the '570 patent is attached as Exhibit B to the complaint, that it identifies Cephalon France as the assignee, that it is entitled "Method for the Production of Crystalline Forms and Crystalline Forms of Optical Enantiomers of Modafinil," and that the '570 patent issued on November 7, 2006. Lupin specifically denies that the PTO duly and legally issued the '570 patent. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding patent ownership and entitlement to sue for infringement, and therefore denies these allegations. Lupin denies any remaining allegations in paragraph 13.

Complaint Paragraph 14: Upon information and belief, Lupin filed ANDA No. 200751 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of armodafinil capsules in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths ("Lupin's generic armodafinil products") before the expiration of the '516 and '570 patents ("patents-in-suit"). On information and belief, as part of its ANDA, Lupin filed a "Paragraph IV Certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the patents-in-suit are "invalid or will not be infringed by the manufacture, use, or sale of" Lupin's generic armodafinil products that are the subject of Lupin's ANDA No. 200751.

Answer: With respect to paragraph 14, Lupin admits only that Lupin Ltd. filed ANDA No. 200751 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of armodafinil tablets in various strengths (50 mg, 100 mg, 150 mg, 200 mg, and 250 mg) and that this ANDA included paragraph IV certifications for the patents in suit. Lupin denies any remaining allegations in paragraph 14.

Complaint Paragraph 15: Lupin caused to be sent to Cephalon a letter ("the Notice Letter"), dated February 5, 2010, notifying Cephalon that Lupin Ltd. had filed ANDA No. 200751 seeking approval to market Lupin's generic armodafinil products prior to the expiration of the patents-in-suit, and was providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Cephalon received the Notice Letter on or about February 8, 2010.

Answer: With respect to paragraph 15, Lupin admits only that Lupin Ltd. caused a notice letter required by statute and regulation to be sent to Cephalon on February 5, 2010 and that this notice letter included the information required by statute and regulation. Lupin denies any remaining allegations in the first sentence in paragraph 15. Lupin is without knowledge or

information sufficient to form a belief as to the truth of the allegations in the second sentence in paragraph 15, and therefore denies them.

Count I for Infringement of the '516 Patent

Complaint Paragraph 16: Cephalon realleges and incorporates by reference paragraphs 1-15.

Answer: With respect to paragraph 16, Lupin repeats and realleges the responses in paragraphs 1 to 15 of the answer and incorporates them by reference.

Complaint Paragraph 17: Lupin has filed or caused to be filed ANDA No. 200751 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic armodafinil products before the expiration of the '516 patent. On information and belief, Lupin also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '516 patent is invalid, unenforceable, or not infringed.

Answer: With respect to paragraph 17, Lupin admits only that Lupin Ltd. filed ANDA No. 200751 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of armodafinil tablets in various strengths (50 mg, 100 mg, 150 mg, 200 mg, and 250 mg) and that this ANDA included a paragraph IV certification for the '516 patent. Lupin denies any remaining allegations in paragraph 17, and denies that Lupin Pharma is a proper party.

Complaint Paragraph 18: By submitting its ANDA No. 200751 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's generic armodafinil products before the expiration of the '516 patent, Lupin Ltd. has infringed the '516 patent under 35 U.S.C. § 271(e)(2).

Answer: Lupin denies the allegations in paragraph 18.

Complaint Paragraph 19: Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA No. 200751 for Lupin's generic armodafini1 products, and in the preparation to sell in the United States Lupin's generic armodafinil products.

Answer: Lupin denies the allegations in paragraph 19.

Complaint Paragraph 20: Upon information and belief, Lupin intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Lupin's generic armodafini1 products with a product insert that will direct physicians and patients in the use of Lupin's generic armodafinil products.

Answer: With respect to paragraph 20, Lupin admits only that its generic armodafinil products will include a package insert for physicians and patients. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 20, and therefore denies them.

Complaint Paragraph 21: Upon information and belief, Lupin's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '516 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

Answer: Lupin denies the allegations in paragraph 21.

Complaint Paragraph 22: Upon FDA approval of Lupin's ANDA No. 200751, Lupin will infringe the '516 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin's generic armodafinil products in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c).

Answer: Lupin denies the allegations in paragraph 22.

Complaint Paragraph 23: Upon information and belief, Lupin Pharma will actively aid, abet, encourage, and induce Lupin Ltd. and others in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

Answer: Lupin denies the allegations in paragraph 23.

Complaint Paragraph 24: Upon information and belief, Lupin Pharma and Lupin Ltd. will both actively participate in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

Answer: Lupin denies the allegations in paragraph 24.

Complaint Paragraph 25: Upon information and belief, the offer to sell, sale, and/or importation of Lupin's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271 (b) of at least one claim of the '516 patent, either literally or under the doctrine of equivalents.

Answer: Lupin denies the allegations in paragraph 25.

Complaint Paragraph 26: Upon information and belief, Lupin had knowledge of the '516 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

Answer: With respect to paragraph 26, Lupin admits only that it had knowledge of the '516 patent before Cephalon filed this lawsuit on March 16, 2010. Lupin denies all other allegations in paragraph 26.

Complaint Paragraph 27: Upon information and belief, the offer to sell, sale, and/or importation of Lupin's generic armodafinil products would contributorily infringe under 35

U.S.C. § 271 (c) at least one of the claims of the '516 patent, either literally or under the doctrine of equivalents.

Answer: Lupin denies the allegations in paragraph 27.

Complaint Paragraph 28: Lupin has knowledge of the '516 patent and is knowingly and willfully infringing the '516 patent.

Answer: With respect to paragraph 28, Lupin admits only that it has knowledge of the '516 patent. Lupin denies all other allegations in paragraph 28.

Complaint Paragraph 29: As a result of Lupin's infringement of the '516 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

Answer: Lupin denies the allegations in paragraph 29.

Count II for Infringement of the '570 Patent

Complaint Paragraph 30: Cephalon realleges and incorporates by reference paragraphs 1-29.

Answer: With respect to paragraph 30, Lupin repeats and realleges the responses in paragraphs 1-29 of the answer and incorporates them by reference.

Complaint Paragraph 31: Lupin has filed or caused to be filed ANDA No. 200751 with the FDA, seeking authorization to manufacture, import, market, use, offer for sale, and sell Lupin's generic armodafinil products before the expiration of the '570 patent. On information and belief, Lupin also filed with the FDA, pursuant to 21 U.S.C. § 355G)(2)(A)(vii)(IV), a certification alleging that the claims of the '570 patent are invalid, unenforceable, or not infringed.

Answer: With respect to paragraph 31, Lupin admits only that Lupin Ltd. filed ANDA No. 200751 with the FDA seeking approval to engage in the commercial manufacture, use, or

sale of armodafinil tablets in various strengths (50 mg, 100 mg, 150 mg, 200 mg, and 250 mg) and that this ANDA included a paragraph IV certification for the '570 patent. Lupin denies any remaining allegations in paragraph 17, and denies that Lupin Pharma is a proper party.

Complaint Paragraph 32: By submitting ANDA No. 200751 under § 505(j) of the Federal Food, Drug, and Cosmetic Act for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's generic armodafinil products before the expiration of the '570 patent, Lupin Ltd. has infringed the '570 patent under 35 U.S.C. § 271(e)(2).

Answer: Lupin denies the allegations in paragraph 32.

Complaint Paragraph 33: Upon information and belief, Lupin Pharma has acted in concert with Lupin Ltd., actively supporting, participating in, encouraging, and inducing Lupin Ltd.'s filing of ANDA No. 200751 for Lupin's generic armodafinil products, and in the preparation to sell in the United States Lupin's generic armodafinil products.

Answer: Lupin denies the allegations in paragraph 33.

Complaint Paragraph 34: Upon information and belief, Lupin intends, soon after the FDA has approved the ANDA, to begin manufacturing, marketing, selling, and offering to sell Lupin's generic armodafinil products with a product insert that will direct physicians and patients in the use of Lupin's generic armodafinil products.

Answer: With respect to paragraph 34, Lupin admits only that its generic armodafinil products will include a package insert for physicians and patients. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 34, and therefore denies them.

Complaint Paragraph 35: Upon information and belief, Lupin's generic armodafinil products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '570 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

Answer: Lupin denies the allegations in paragraph 35.

Complaint Paragraph 36: Upon FDA approval of Lupin's ANDA No. 200751, Lupin will infringe the '570 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Lupin's generic armodafinil products in the United States, and by actively inducing infringement by others under 35 U.S.C. § 271(b).

Answer: Lupin denies the allegations in paragraph 36.

Complaint Paragraph 37: Upon information and belief, Lupin Pharma will actively aid, abet, encourage, and induce Lupin Ltd. and others in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

Answer: Lupin denies the allegations in paragraph 37.

Complaint Paragraph 38: Upon information and belief, Lupin Pharma and Lupin Ltd. will both actively participate in the production, importation, sale, offer for sale, and use of Lupin's generic armodafinil products.

Answer: Lupin denies the allegations in paragraph 38.

Complaint Paragraph 39: Upon information and belief, the offer to sell, sale, and/or importation of Lupin's generic armodafinil products would actively induce infringement under 35 U.S.C. § 271 (b) of at least one claim of the '570 patent, either literally or under the doctrine of equivalents.

Answer: Lupin denies the allegations in paragraph 39.

Complaint Paragraph 40: Upon information and belief, Lupin had knowledge of the '570 patent and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '570 patent, either literally or under the doctrine of equivalents.

Answer: Lupin admits only that it had knowledge of the '570 patent before Cephalon filed this lawsuit on March 16, 2010. Lupin denies all other allegations in paragraph 40.

Complaint Paragraph 41: The Notice Letter lacks any factual basis for non-infringement of any claim of the '570 patent.

Answer: With respect to paragraph 41, Lupin denies that the Notice Letter concedes liability for infringement of the '570 patent and admits only that the Notice Letter does not discuss a noninfringement defense for the '570 patent. Lupin denies any remaining allegations in paragraph 41.

Complaint Paragraph 42: Lupin has knowledge of the '570 patent and is knowingly and willfully infringing the '570 patent.

Answer: With respect to paragraph 42, Lupin admits only that it has knowledge of the '570 patent. Lupin denies all other allegations in paragraph 42.

Complaint Paragraph 43: As a result of Lupin's infringement of the '570 patent, Cephalon has been and will continue to be damaged unless said infringement is enjoined by this Court. Cephalon has no adequate remedy at law.

Answer: Lupin denies the allegations in paragraph 43.

Defenses

Responding further to the complaint, without any admission as to the burden of proof and without any admission as to any of the averments in the complaint, Lupin sets forth the following defenses:

First Defense
(Noninfringement of the Patents in Suit)

The ’516 and ’570 patents’ claims do not, either literally or under the doctrine of equivalents, cover Lupin’s generic armodafinil products or any methods of using Lupin’s generic armodafinil products. Thus, Lupin has not infringed and will not infringe either the ’516 patent or the ’570 patent by making, using, selling, offering for sale, marketing, or importing any drug products according to ANDA No. 200751.

Second Defense
(Invalidity of the Patents in Suit)

The ’516 and ’570 patents and all their claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

Third Defense
(Additional Defenses from Discovery)

Lupin includes any and all additional defenses and counterclaims that discovery may reveal, such as unenforceability of the ’516 patent and patent misuse.

Fourth Defense
(Lack of Subject-Matter Jurisdiction for Certain Claims)

The court lacks subject-matter jurisdiction over any and all claims based on 35 U.S.C. § 271(a), § 271(b), and § 271(c) because Lupin Ltd. and Lupin Pharma have engaged in no acts purported to directly infringe, contributorily infringe, or induce infringement of any patent in suit.

Fifth Defense
(Lack of Subject-Matter Jurisdiction Based on Acts by Lupin Pharma)

The court lacks subject-matter jurisdiction over any and all claims directed to Lupin Pharma. Thus, Lupin Pharma is not a proper party.

COUNTERCLAIM

Lupin Pharmaceuticals, Inc. ("Lupin Pharma") and Lupin Limited ("Lupin Ltd.") (collectively "Lupin") by way of counterclaim against Plaintiffs, Cephalon, Inc. and Cephalon France (collectively "Cephalon"), state:

The Parties

1. Lupin Pharma is a Virginia corporation with its principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

2. Lupin Ltd. is an Indian corporation with an address at B/4 Laxmi Towers Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

3. On information and belief, Cephalon, Inc. is a Delaware corporation having its corporate offices and principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

4. On information and belief, Cephalon France, is a société par actions simplifiée ("SAS") under the laws of France, a wholly-owned subsidiary of Cephalon, Inc., and located at 20 Rue Charles Martigny, 94701 Maisons-Alfort Cedex, France.

Jurisdiction and Venue

5. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Lupin seeks declaratory relief, i.e., a declaration that the patents in suit are not infringed and that they are invalid. Thus, Lupin asserts substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq*.

6. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

Factual Background

8. United States Patent No. RE37,516 ("the '516 patent"), entitled "Acetamide Derivative Having Defined Particle Size," was issued on January 15, 2002.

9. United States Patent No. 7,132,570 ("the '570 patent"), entitled "Method for the Production of Crystalline Forms and Cyrstalline Forms of Optical Enantiomers of Modafinil," was issued on November 7, 2006.

10. Cephalon alleges that the '516 patent is assigned to Cephalon, Inc.

11. Cephalon alleges that the '570 patent is assigned to Cephalon France.

12. On information and belief, Cephalon, Inc. is the holder of approved New Drug Application ("NDA") No. 21-875 for Nuvigil® (armodafinil) tablets in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths for certain FDA-approved indications.

13. Lupin Ltd. holds Abbreviated New Drug Application ("ANDA") No. 200751 for armodafinil tablets containing 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg of armodafinil.

First Count
(Declaration of Noninfringement)

14. Lupin repeats and realleges paragraphs 1 through 13 of the counterclaim.

15. Cephalon has asserted the '516 and '570 patents against Lupin. Cephalon maintains—and Lupin denies—that the '516 and '570 patents cover Lupin's generic armodafinil products and methods of using Lupin's generic armodafinil products.

16. The '516 and '570 patents' claims do not cover, either literally or under the doctrine of equivalents, Lupin's generic armodafinil products or any methods of using Lupin's generic armodafinil products. Thus, Lupin has not infringed and will not infringe either the '516 patent or the '570 patent by making, using, selling, offering for sale, marketing, or importing any drug products according to ANDA No. 200751.

17. Lupin and Cephalon have adverse legal interests, and there is a substantial controversy between Lupin and Cephalon of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the noninfringement of the ’516 and ’570 patents.

18. Lupin is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of any drug products according to ANDA No. 200751 does not infringe either the ’516 patent or the ’570 patent.

Second Count
(Declaration of Invalidity)

19. Lupin repeats and realleges paragraphs 1 through 18 of the counterclaim.

20. The ’516 and ’570 patents and all their claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

21. Cephalon maintains—and Lupin denies—that the ’516 and ’570 patents are valid.

22. Lupin and Cephalon have adverse legal interests, and there is a substantial controversy between Lupin and Cephalon of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the ’516 and ’570 patents.

23. Lupin is entitled to a judicial declaration that the ’516 and ’570 patents are invalid.

Prayer for Relief

WHEREFORE, Lupin demands judgment in its favor and against Cephalon, Inc. and Cephalon France as follows:

(a) Dismissing the complaint with prejudice and denying each request for relief made by Cephalon, Inc. and Cephalon France;

(b) Declaring the '516 patent not infringed by the submission of ANDA No. 200751 and not infringed by the making, use, sale, offer for sale, marketing, or importation of any drug products according to ANDA No. 200751;

(c) Declaring the '570 patent not infringed by the submission of ANDA No. 200751 and not infringed by the making, use, sale, offer for sale, marketing, or importation of any drug products according to ANDA No. 200751;

(d) Declaring the '516 patent and all its claims invalid;

(e) Declaring the '570 patent and all its claims invalid;

(f) Enjoining Cephalon, Inc. and Cephalon France, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with either plaintiff from threatening to assert or otherwise attempting to enforce either the '516 patent or the '570 patent against Lupin, its customers, suppliers, or anyone in privity with Lupin;

(g) Adjudging that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Lupin its attorney fees;

(h) Awarding Lupin its costs and expenses; and

(i) Awarding Lupin such other and further relief as the Court deems just and proper.

Dated: March 31, 2010

BAYARD, P.A.

/s/ Stephen B. Brauerman

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